

### Comprehensive Technical Resource Sheet for the Full Range of InSpec N10 Liquid Formats.



#### Features

- Designed for cleaning floors, walls, ceiling and other hard surfaces
- For the removal of general process derived residue and soiling
- Rapid action alkaline detergent
- Validated 6 months 'in-use' sterility for trigger spray sterile formats
- Trigger spray formats presented as protected systems
- Ready-to-use (RTU) formats manufactured with Water for Injection
- Multiple bags for cleanroom transfer
- RTU and Concentrated formats available
- Manufactured in accordance with GMP

#### Formulation

InSpec N10 is an alkaline detergent. Ready-to-use formats blended with Water for Injection (WFI).

#### Instructions for Use

InSpec N10 is designed for spraying, wiping and mopping applications.

Spray Bottles: Hold approximately 15cm to 20cm from area to be treated. Apply to surface to ensure complete coverage.

Screw Top Bottles: Pour into an appropriate container for mopping. Apply to surface to ensure complete coverage. 100ml concentrate added to 2.4L of water is required for mopping.

#### Material Compatibility

Application of solutions, when used as directed, will not affect materials normally encountered in the cleanroom. See compatibility information in the Technical File.

#### Safe Handling and Storage Information

Always wear gloves and goggles or face protection. Always read the label and SDS before use.

Store upright in original closed containers, away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is available in the Safety Data Sheet (SDS).

#### Formulation Batch Release Specifications

Specification	Release Parameters
<b>RTU Formats</b>	
SG	1.004 - 1.054
pH	12.1 - 13.4
Colour	Yellow Tint
Clarity	Clear
Odour	Detergent
<b>Concentrate Formats</b>	
SG	1.129 - 1.185
pH	13.7 - 14.4
Colour	Yellow Tint
Clarity	Clear
Odour	Detergent

#### Manufacturing Process

InSpec N10 is manufactured in accordance with GMP in an ISO 5 cleanroom. The solution is filtered through a 0.2-micron filter at point of fill.

#### Sterility

The sterile formats of InSpec N10 are gamma irradiated to a validated process (20-50kGy for 5L products, 25-45kGy for all other formats) to give a sterility assurance level SAL of 10<sup>-6</sup>.

Sterile InSpec N10 products are tested for sterility for batch release.

The trigger spray formats have a validated 6-months 'in-use' sterility. The contents are protected using a membrane-filter trigger.

For screw cap formats, use the entire contents in one session/4-hours to ensure sterility.

Products are double-bagged for the cleanroom transfer process.

#### Certificates

Each batch of InSpec N10 is provided with a Certificate of Analysis (COA) confirming batch release specifications and providing batch manufacturing information.

The COAs for Sterile InSpec N10 products contain information regarding the irradiation of the batch and sterility test results.



## Formats Available

The following formats of InSpec N10 are available:

Product	Code	Cap	Case Size	Container Material	Bags and Material
<b>Sterile Formats</b>					
InSpec N10 1L	N10WF11CC-1LS	Trigger	6 x 1L Bottles	HDPE	Double-Bagged LDPE
InSpec N10 1L Dose	N10WFIDOSE-1LS	Screw Cap	6 x 1L Bottles	HDPE	Double-Bagged LDPE
InSpec N10 5L	N10WF11-5LS	Screw Cap	2 x 5L Bottles	HDPE	Double-Bagged LDPE
InSpec N10 Concentrate 100ml	N10WF11-100MLS	Screw Cap	50 x 100ml Bottles	HDPE	Double-Bagged LDPE
<b>Non-Sterile Formats</b>					
InSpec N10 1L Non-Sterile	N10WF11-1LS	Trigger	6 x 1L Bottles	HDPE	Double-Bagged LDPE
InSpec N10 5L Non-Sterile	NSN10WF1-5L	Screw Cap	2 x 5L Bottles	HDPE	Double-Bagged LDPE
InSpec N10 Concentrate 100ml Non-Sterile	NSN10CONC-100ML	Screw Cap	50 x 100ml Bottles	HDPE	Double-Bagged LDPE
InSpec N10 Concentrate 1L Non-Sterile	N101-1CONC	Trigger	6 x 1L Bottles	HDPE	Double-Bagged LDPE

## Transport Information

Product	Code	Case Dimensions	Commodity Code	Cases per Pallet Euro/UK	Dangerous Goods*
<b>Sterile Formats</b>					
InSpec N10 1L	N10WF11CC-1LS	27cm x 19cm x 33cm 6.4Kg	34029090	64/60	Not classified as hazardous for transport
InSpec N10 1L Dose	N10WFIDOSE-1LS	27cm x 19cm x 33cm 6.4Kg	34029090	64/60	Not classified as hazardous for transport
InSpec N10 5L	N10WF11-5LS	29cm x 20.5cm x 31cm 10.8Kg	34029090	44/51	Not classified as hazardous for transport
InSpec N10 Concentrate 100ml	N10WF11-100MLS	24cm x 24cm x 24cm 5.9Kg	34029090	60/80	UN 1824 Limited Quantity
<b>Non-Sterile Formats</b>					
InSpec N10 1L Non-Sterile	N10WF11-1LS	27cm x 19cm x 33cm 6.4Kg	34029090	64 / 60	Not classified as hazardous for transport
InSpec N10 5L Non-Sterile	NSN10WF1-5L	29cm x 20.5cm x 31cm 10.8Kg	34029090	44 / 51	Not classified as hazardous for transport
InSpec N10 Concentrate 100ml Non-Sterile	NSN10CONC-100ML	24cm x 24cm x 24cm 5.9Kg	34029090	60 / 80	UN 1824 Limited Quantity
InSpec N10 Concentrate 1L Non-Sterile	N101-1CONC	27cm x 19cm x 33cm 6.4Kg	34029090	64 / 60	UN 1824 Limited Quantity

\*Limited quantity applies to inner packaging of 1L or less for products classed as UN 1824